K032300

OCT - 9 2003

510(k) Summary

Accolade™-J Hip Stem Series

Proprietary Name:	Accolade™-J Hip Stem Series
Common Name:	Artificial Hip Component
Classification Name and Reference:	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Device Product Code:	87 MEH, LZO
Predicate Proprietary Name:	Accolade™ TMZF® HA Hip Stems and Accolade™ TMZF® HA Plus Hip Stems Omnifit® M-HA Hip Stems
Predicate Regulatory Class:	Class II
Predicate Product Code:	87 MEH
For Information contact:	Lorraine Montemurro Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 Phone: (201) 831-5892 Fax: (201) 831-6038

Description/Technological Comparison

The subject Accolade™-J Hip Stems feature the geometry of the predicate TMZF® HA Hip Stems and Accolade™ TMZF® Plus HA Hip Stems, but feature the same substrate material and same HA coating as the predicate Omnifit® M-HA Hip Stems.

K032300

Intended Use

The subject hip stems are single-use devices intended for cementless fixation. They are intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. These devices are intended for use with any currently available Howmedica Osteonics acetabular component and V40® femoral heads labeled for use with V40® Titanium stems. The indications for use remain identical to those of the predicate devices, and are restated here.

Indications:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,
- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Testing Summary

Finite Element Analysis (FEA) was used to evaluate the strength of the neck and body regions of the subject Accolade™-J Hip Stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Ms. Lorraine Montemurro
Regulatory Affairs Manager
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Re: K032300
Trade/Device Name: Accolade™-J Hip Stem Series
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: II
Product Code: MEH and LZO
Dated: July 24, 2003
Received: August 6, 2003

Dear Ms. Montemurro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032300

Device Name: Accolade™-J Hip Stem Series

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- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____(Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032300